Information Regarding Management Objectives and Assessment Endpoints

Submitted to the Portland Harbor Governmental Eco-Team
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The information in this package is comprised of two sorts 1) examples of management goals/objectives from 4 different sites including some with assessment endpoints and 2) EPA guidance relevant to the development of such goals/objectives and assessment endpoints.

According to EPA guidance the development of management goals/objectives for the ecological risk assessment process is a key step in problem formulation and helps provide a logical framework for the ecological risk assessment. Management objectives can encompass those that are explicitly required by the law and those that are appropriate to the community context. As Bert explained at the last meeting, assessment endpoints ideally are those relevant to consideration of whether or not management goals/objectives are being met. Excerpts from the EPA Risk Assessment and Eco endpoints guidances have been included for your review.

Table of Contents

PUBLIC REVIEW DRAFT

CLARK FORK RIVER ECOLOGICAL RISK ASSESSMENT

December 1999

Prepared for

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TABLE OF CONTENTS

from agricultural lands. Because these chemicals are not related to tailings or other mining wastes, they are not formally evaluated as chemicals of potential concern. However, their potential impact is considered as part of the process of evaluating cause-and-effect relationships between environmental contamination and adverse effects on the ecosystem.

In addition to nutrients, the aquatic community may be affected by factors such as water withdrawal, elevated water temperature, dissolved oxygen level, and sediment deposition. Likewise, the terrestrial community can be impacted by overgrazing and run-off of agricultural chemicals applied to ranch or farmland. When data permit, this risk assessment seeks to evaluate the importance of these potentially important confounding factors that may act independently or interact with the effects of metals on ecological receptors.

3.4 CONCEPTUAL MODEL: ECOSYSTEMS AND RECEPTORS POTENTIALLY AT RISK

Most metals and metalloids are capable of causing adverse effects on a wide variety of environmental receptors. Based on the known pattern of tailings deposits along the Clark Fork River and in the adjacent flood plain (ARCO 1998b), it is evident that the potential for adverse effects exists both for the aquatic ecosystem (fish, benthic invertebrates, amphibians, aquatic plants, etc.) and the terrestrial ecosystem (land animals, birds, insects, trees, grasses, shrubs, etc), both within and outside the riparian area.

Figure 3-3 is a conceptual site model showing how mining-related contaminants may come into contact with both aquatic and terrestrial receptors. This figure illustrates the complex pathways by which chemical contaminants may pass from one portion of the ecosystem to another, and the multiple points at which mining-related chemicals might impact the ecosystem.

3.5 RISK MANAGEMENT GOALS

Risk management goals define the ecological values to be protected and help ensure that the risk assessment process will supply the information needed to support the risk management decision process. Risk managers and risk assessors used information on the area ecology, regulatory endpoints, and publicly perceived environmental values to derive the management goals for this assessment. Public input was gathered during numerous regional meetings held by the US EPA. The ecological risk assessment subgroup responsible for guiding this assessment was directed by Dr. Chris Weis, Regional Toxicologist for EPA Region VIII, and included representatives from the US EPA office in Helena, Montana, the USDOI Fish and Wildlife Service, the Montana State Department of Environmental Quality, counties within the Operable Unit, the Confederated Salish and Kootenai Tribes, and ARCO and their environmental consultants. Based on the results of inputs from all of these parties, the overall management goal for this site was defined as follows:

> "Maintain and improve the integrity of all ecological systems within the spatial boundaries of the Clark Fork River Operable Unit, CFR OU, by protecting them from the deleterious effects of acute and chronic exposures to chemicals of concern and other chemical, physical and biological stressors."

The general management goal above was refined into more specific subgoals for use by the risk assessors in defining assessment endpoints. Assessment endpoints are the measurable ecological values to be protected. For specific assessment endpoints, risk hypotheses are evaluated using measures of exposure, effects, and ecosystem characteristics. The results of evaluating risk hypotheses are reported in the risk analysis and risk characterization phases so that risk management decisions can be made based on the weight of evidence provided. Specific management subgoals identified for this site are listed below:

a. Maintain and improve the biological integrity of the native and introduced fisheries populations, by protecting them from the deleterious effects of acute and chronic exposures to chemicals of concern and other chemical, physical and biological stressors.

b. Maintain and improve the biological integrity of semi-aquatic and aquatic macroinvertebrate, periphyton, and aquatic vascular plant communities by protecting them from the deleterious effects of acute and chronic exposures to chemicals of concern and other chemical, physical and biological stressors.

c. Maintain and improve the biological integrity of terrestrial plant communities, including native, introduced, and agricultural plant communities, by protecting them from the deleterious effects of acute and chronic exposures to chemicals of concern and other chemical, physical and biological stressors.

d. Maintain and improve migratory birds, terrestrial and semi-aquatic wildlife populations, and livestock by protecting them from the deleterious effects of acute and chronic exposures to chemicals of concern and other chemical, physical and biological stressors.

e. Ensure protection of threatened and endangered species (including candidate species) and species of special concern and their habitats by protecting them from the deleterious effects of acute and chronic exposures to chemicals of concern and other chemical, physical and biological stressors.

3.6 ASSESSMENT ENDPOINTS

Assessment Endpoints are derived from general and specific management goals, and identify the specific environmental values which the risk manager has selected to be protected at the site. Specific Assessment Endpoints selected by the risk manager following a consideration of advice and input from a number of concerned parties at this site are listed below:

Assessment Endpoints for Terrestrial Receptors

- Survival, growth, diversity and abundance of the riparian vegetation community under chronic exposure to contaminants and other chemical and physical stressors in the 100 year flood plain habitats of the Clark Fork River.

- Survival, growth, and reproduction of wildlife populations under chronic exposure to contaminants and other chemical and physical stressors in the 100 year flood plain habitats of the Clark Fork River.

Assessment Endpoints for Aquatic Receptors

- Survival of fish, aquatic invertebrates, and algal populations under acute exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River.

- Survival, growth and reproduction of fish, aquatic invertebrates, and algal populations under chronic exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River.

Assessment Endpoints for Species of Special Concern

- Survival and reproduction of the bald eagle under chronic exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River Operable Unit.

- Survival and reproduction of the bull trout under acute and chronic exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River.

3.7 RECEPTORS

In general, Assessment Endpoints can not be measured directly, so certain indicator species or groups of species are selected to represent each ecosystem identified as an assessment endpoint. At this site, the receptors selected for evaluation are listed below:

Terrestrial Receptors

- White-tailed Deer
- Deer Mouse

Couer D’Alene

Evaluation of the ERA in the Coeur d'Alene River Basin

The following subsections evaluate EPA's ERA for the Coeur d'Alene River Basin with respect to consistency with agency guidance.

Problem Formulation

Section 2 of the ERA, which documents the problem formulation step, begins with a statement of management objectives and then derives assessment end points from those objectives and develops a conceptual model. The management objectives were developed with input from an ERA work group consisting of representatives of the states of Idaho and Washington; the Coeur d'Alene, Spokane, and Colville tribes; the U.S. Fish and Wildlife Service; and any other governmental or nongovernmental organizations that wished to participate.

Contaminants of potential ecological concern (COPECs) were selected using a two-step procedure. In the first step, the available data on concentrations of chemicals in soil, sediment, and surface water were subjected to a data quality review. Resultant values were then screened against soil/sediment background levels and ambient water-quality criteria.

The assessment end points include individual species, biological communities, and physical habitat characteristics that could be adversely affected by mining-related hazardous substances. Taxonomic groups of organisms addressed included birds, mammals, fish, amphibians, and plants. Representative species belonging to each group were identified for each Conceptual Site Model (CSM)[2] unit and habitat type. The measures of mining-related effects selected for evaluation included reductions in survival, reproduction, growth, and abundance. For migratory birds and "special status" species (i.e., threatened, endangered, or culturally significant species, or state or agency species of special concern) effects of mining-related hazardous substances on the health of individual organisms were also evaluated. For migratory birds and special status species, effects were considered to be adverse if any of the attributes of interest was observed or predicted to be adversely affected. For other species, effects were considered adverse only if a 20% or greater adverse change in an attribute of interest was observed or predicted. The use of a 20% effects level as a default de minimis criterion for ecological significance was first proposed by Suter et al. (1995), on the grounds that this value is consistent both with EPA's regulatory practices and with the practical detection limits of typical toxicity testing protocols and field survey methods.

In addition to evaluating effects of mining-related hazardous substances on individual species, the ERA also evaluated effects on aquatic and terrestrial plant and invertebrate communities, soil processes, and physical/biological characteristics. Community-level effects addressed included effects on community composition, abundance, density, species diversity, and community structure. Physical/biological characteristics evaluated included habitat suitability indices, spatial distributions of healthy riparian communities, sediment deposition rates, and turbidity. Changes in these characteristics were addressed to account for secondary effects of hazardous substance releases (e.g., degradation of riparian habitat resulting from toxic effects of hazardous substances on vegetation).

[2] The study area was divided into five CSM units in the ERA. These roughly correspond to the high-gradient watersheds in the upper (eastern) basin (CSM 1), the mid-gradient watersheds in the middle basin (CSM 2), the expansive depositional floodplain and lateral lakes area in the lower basin (CSM 3), Lake Coeur d'Alene (CSM 4), and the Spokane River (CSM 5); see Chapters 3 and 4 of this report for further discussion.

4. The receptor is reflective and representative of the assessment end points for the Coeur d'Alene River Basin,
5. The receptor is known to be either sensitive or highly exposed to the toxic metals in the Coeur d'Alene River Basin.

Section 2.3 of the ERA also identifies federally listed and state-listed or candidate species potentially present within the study area. This section also summarizes previous studies of biological conditions and metal contamination throughout the basin. This information appears to be adequate to identify representative species and communities for use in the risk assessment, although not sufficient to fully characterize risks to all of these receptors.

Management Goals, Assessment/Measurement End Points, and Conceptual Model

EPA consulted with other agencies and stakeholders in development of the following two management goals for the site:

- Maintenance (or provision) of soil, sediment, water-quality, food source, and habitat conditions capable of supporting a "functional ecosystem" for the aquatic and terrestrial plant and animal populations in the Coeur d'Alene River Basin
- Maintenance (or provision) of soil, sediment, water-quality, food source, and habitat conditions supportive of individuals of special-status biota (including plants and animals) and migratory birds (species protected under the Migratory Bird Treaty Act) that are likely to be found in the Coeur d'Alene River Basin.

The risk assessment team then developed assessment end points at the individual, population, community, and habitat/ecosystem/landscape levels intended to support these goals.

Individual-level end points included migratory bird species and threatened or endangered species covered under the second of the above goals. These types of species are protected by statute (the Migratory Bird Treaty Act and the Endangered Species Act), and detrimental effects on the health, survival, growth, or reproduction of any individual belonging to such species are considered adverse. The remaining assessment end points relate to the first goal. Population-level assessment end points included various species of birds, mammals, fish, amphibians, and plants. For these species, effects were considered adverse if key population attributes such as reproduction, survival, growth, or abundance were to be reduced by 20% or more, or if greater than 20% of the individuals present in a population could be affected. Community-level end points included aquatic and terrestrial plant communities and aquatic and terrestrial invertebrate communities. For these end points, individual species were not identified. Effects were considered adverse if there was greater than a 20% reduction in key community-level attributes. Habitat/ecosystem/landscape-level end points included soil process and physical and biological landscape attributes. Effects on soil processes were considered adverse if measures of soil microbial function or other measurable soil processes were reduced by 20% or more. Effects on physical and biological characteristics were considered adverse if any measurable level of degradation of habitat structure occurred.

Specific measures of exposure defined for the site included concentrations of chemicals in sediment, soil, surface water, and biota. The types of assessment end points found in each CSM unit and habitat type were summarized (CH2M-Hill and URS Corp. 2001, table 2-1), and a variety of specific attributes that could be adversely affected by chemical exposures were identified for each assessment end point.

Indirect effects of chemicals that occur as secondary effects of alterations in physical and biological ecosystem characteristics were discussed.

A conceptual model was developed (CH2M-Hill and URS Corp. 2001, figures 2-15 to 2-21) showing, for each CSM unit, the linkages between sources and assessment end points. Both chemical and physical effects of mining are included in these figures.

It could be argued that the extensive list of assessment end points developed for this ERA is excessively complex, given the obvious and well-documented impairment of aquatic and terrestrial biota throughout the basin. However, these end points are clearly related to the management goals and appear to be sufficient to support the subsequent analysis of ecological exposures and effects.

Analysis

The analysis phase of an ERA includes consideration of all relevant aspects of the environmental transport, fate, and effects of a hazardous substance release, as identified in the problem formulation section of the risk assessment. The analysis is conceptually separated into an "exposure" assessment and an "effects" assessment, although these two assessment components are necessarily closely linked. This section of the report addresses the technical adequacy of the exposure and effects analyses documented in the ERA.

Exposure Analysis

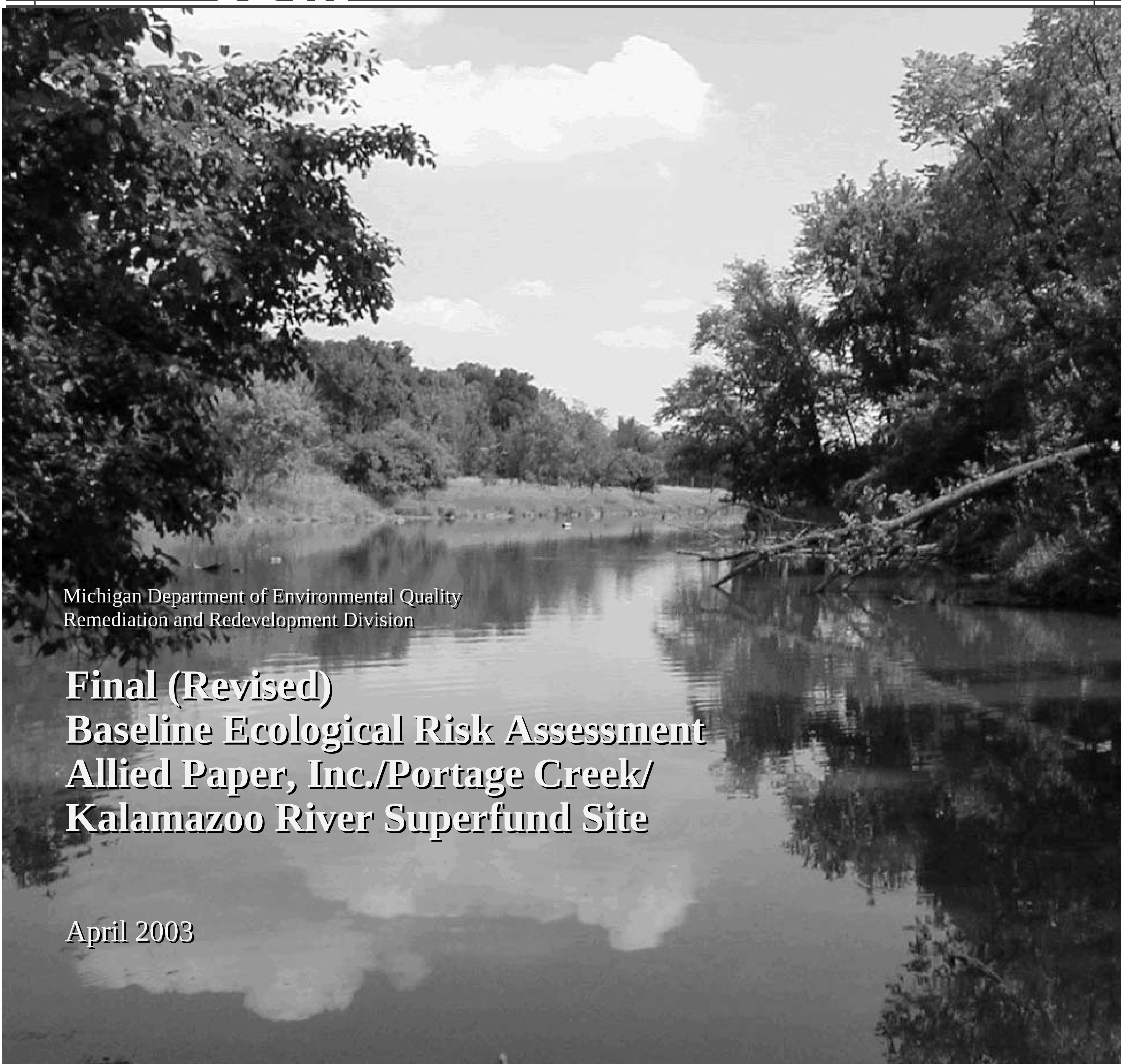
This section addresses the adequacy of the exposure assessment component of the ERA. Questions to be addressed include whether all the significant exposure pathways were identified, whether physical transport processes and environmental transformations were adequately characterized, and whether seasonal and spatial variability were adequately addressed.

Environmental Transport

The ERA was developed in tandem with the RI (URS Greiner, Inc. and CH2M Hill 2001a) and, as stated in the ERA, "some information briefly presented in the [ERA] will be presented in greater detail in the RI/FS" (CH2M-Hill and URS Corp. 2001, p. 1-1). In this case, the RI describes the magnitude and location of metals contamination in the basin and presents information about their disposition (see chapter 4 of this report for evaluation of the RI). Extensive previous studies over a period of several decades and those conducted in support of the RI inform the characterization of contaminants and their transport through the basin. A database of metals concentrations in surface water was compiled for the RI from which expected values for metals loading through the basin were determined.[3] Metals loading diagrams are presented in the ERA and demonstrate that the original Bunker Hill Superfund site (the box) is the portion of the system contributing the largest loads of dissolved zinc, followed by Canyon and Ninemile

[3] The database of environmental metals concentrations used to provide expected loading values in the RI is not the same database used to estimate exposure point concentrations in the ERA (although similar information is presented in both databases). The committee did not seek to evaluate the differences in these two data sets, except as noted below in the section "Dose Quantification."

CDM



Michigan Department of Environmental Quality
Remediation and Redevelopment Division

Final (Revised)
Baseline Ecological Risk Assessment
Allied Paper, Inc./Portage Creek/
Kalamazoo River Superfund Site

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assessors and often consider guidance from relevant regulatory agencies. ERA-related remedial action goals and objectives for the API/PC/KR have been determined by MDEQ, and include:

1. The establishment and maintenance of a healthy and diverse aquatic ecosystem in and adjacent to the API/PC/KR site
2. Reductions in PCB concentrations in fish and wildlife such that human consumption restrictions can be lifted

Site-specific remedial action goals and objectives should include:

1. The removal from the environment and isolation of all PCB-contaminated soils, sediments, and groundwater to a level that will achieve state water quality standards in the Kalamazoo River and Portage Creek (0.000026 μg/L for human health and 0.00012 μg/L for wildlife)
2. Remediation until residual levels in the environment are so low that healthy, safe-to-consume (e.g. no fish fillets greater than 2 ppm), self-reproducing, and ecologically diverse fish and wildlife populations can return to and survive in the Kalamazoo River basin

The Michigan Department of Environmental Quality suggests that water, soil, and whole fish cleanup objectives be set at current minimum detectable levels of 0.33 ppm. These are to be achieved while avoiding or minimizing a loss of floodway/floodplain capacity, reductions in river channel length, or loss of wetland values. Assessment endpoints are described as explicit expressions of the environmental variable(s) that are to be protected. The characteristics of the contaminants of concern, toxic mechanisms, and exposure pathways were used to select the following assessment endpoints:

- Preservation of the fish populations (e.g., smallmouth bass and white sucker) and communities utilizing the Kalamazoo River and Portage Creek system
- Preservation of the survival, growth, and reproductive capacity of aquatic receptors (e.g., aquatic plants, benthic macroinvertebrates, fish, larval amphibians) utilizing the Kalamazoo River and Portage Creek system
- Preservation of the survival, growth, and reproductive capacity of mammalian receptors (e.g., mouse, mink, muskrat, red fox) utilizing the Kalamazoo River and Portage Creek system
- Preservation of the survival, growth, and reproductive capacity of avian receptors (e.g., robin, bald eagle, and great-horned owl) utilizing the Kalamazoo River and Portage Creek system

Waquoit Bay

Text Box 2-6. Management Goals for Waquoit Bay

A key challenge for risk assessors when dealing with a general management goal is interpreting the goal for a risk assessment. This can be done by generating a set of management objectives that represent what must be achieved in a particular ecosystem in order for the goal to be met. An example of this process was developed in the Waquoit Bay watershed risk assessment (U.S. EPA, 1996a).

Waquoit Bay is a small estuary on Cape Cod showing signs of degradation, including loss of eelgrass, fish, and shellfish and an increase in macroalgae mats and fish kills. The management goal for Waquoit Bay was established through public meetings, preexisting goals from local organizations, and State and Federal regulations:

> Reestablish and maintain water quality and habitat conditions in Waquoit Bay and associated freshwater rivers and ponds to (1) support diverse self-sustaining commercial, recreational, and native fish and shellfish populations and (2) reverse ongoing degradation of ecological resources in the watershed.

To interpret this goal for the risk assessment, it was converted into 10 management objectives that defined what must be true in the watershed for the goal to be achieved and provide the foundation for management decisions. The management objectives are:

- Reduce or eliminate hypoxic or anoxic events
- Prevent toxic levels of contamination in water, sediments, and biota
- Restore and maintain self-sustaining native fish populations and their habitat
- Reestablish viable eelgrass beds and associated aquatic communities in the bay
- Reestablish a self-sustaining scallop population in the bay that can support a viable sport fishery
- Protect shellfish beds from bacterial contamination that results in closures
- Reduce or eliminate nuisance macroalgal growth
- Prevent eutrophication of rivers and ponds
- Maintain diversity of native biotic communities
- Maintain diversity of water-dependent wildlife

From these objectives, eight ecological entities and their attributes in the bay were selected as assessment endpoints (see section 3.3.2) to best represent the management goals and objectives, one of which is *areal extent and patch size of eelgrass beds*. Eelgrass was selected because (1) scallops and other benthic organisms and juvenile finfish depend directly on eelgrass beds for survival, (2) eelgrass is highly sensitive to excess macroalgal growth, and (3) abundant eelgrass represents a healthy bay to human users.

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Generic Ecological Assessment Endpoints (GEAEs)

for Ecological Risk Assessment

Risk Assessment Forum
U.S. Environmental Protection Agency
Washington, DC 20460

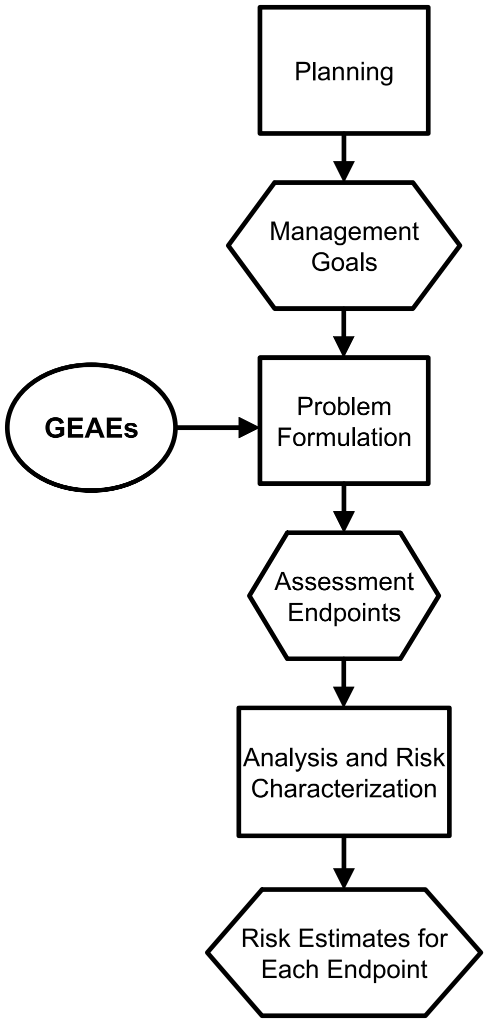

Figure 1-1. Application of generic ecological assessment endpoints (GEAEs) in risk assessment. The process of generating and using ecological assessment endpoints and showing how GEAEs are used along with management goals in the selection of assessment endpoints during problem formulation. Rectangles represent assessment processes and hexagons represent the products of those processes.

important fish species, such as coho salmon, with its attributes being fecundity and recruitment. Effects on assessment endpoints are estimated using measures of effects (see text box). The guidelines provide three selection criteria: ecological relevance, susceptibility (exposure plus sensitivity), and relevance to management goals. Selecting appropriate assessment endpoints is a critical step in ensuring that an assessment will be useful to risk managers in making informed

Similarly, kills of organisms have short-term effects on population abundance but do not necessarily have a significant or long-term effect on abundance. The methods for determining

Table 2-1. Generic ecological assessment endpoints[a]

Entity	Attribute	Identified EPA precedents
Organism-level endpoints		
Organisms (in an assessment population or community)	Kills (mass mortality, conspicuous mortality)	Vertebrates
	Gross anomalies	Vertebrates Shellfish Plants
	Survival, fecundity, growth	**Endangered species** **Migratory birds** **Marine mammals** **Bald and golden eagles** Vertebrates Invertebrates Plants
Population-level endpoints		
Assessment population	Extirpation	Vertebrates
	Abundance	Vertebrates Shellfish
	Production	Vertebrates (game/resource species) Plants (harvested species)
Community and ecosystem-level endpoints		
Assessment communities, assemblages, and ecosystems	Taxa richness	Aquatic communities **Coral reefs**
	Abundance	Aquatic communities
	Production	Plant assemblages
	Area	**Wetlands** **Coral reefs** Endangered/rare ecosystems
	Function	**Wetlands**
	Physical structure	Aquatic ecosystems
Officially designated endpoints		
Critical habitat for threatened or endangered species	Area	
	Quality	
Special places	Ecological properties that relate to the special or legally protected status	e.g., **National parks, national wildlife refuges, Great Lakes**

[a]Generic ecological assessment endpoints for which EPA has identified existing policies and precedents, in particular the specific entities listed in the third column. Bold indicates protection by federal statute. See Table 4-1 for additional endpoints that could be considered by EPA in the future.

Table 2-2. Generic ecological assessment endpoints (GEAEs): summary of the policy support for their use and their practicality[a]

GEAE #	Entity: attribute(s)	Policy support	Practicality
Organism-level endpoints			
1	Organisms: kills (mass mortality, conspicuous mortality)	Supported by many EPA programs; e.g., EPA has restricted the use of pesticides (e.g., diazinon and carbofuran) due to incidents of bird mortality.	Likelihood of kills from chemical pollutants can be estimated from toxicity testing. Incidents may be easy or difficult to observe, but when seen, they suggest a common mechanism or stressor exerting a strong effect.
2	Organisms: gross anomalies	Gross anomalies in birds, fish, shellfish, and other organisms are a cause for public concern and have been the basis for EPA regulatory action and guidance (e.g., assessed at Superfund sites, incorporated into biocriteria for water programs).	External gross anomalies are readily observed and are commonly included in survey protocols for fish and forests. They are also reported in toxicity tests of fish, birds, mammals, and plants.
3	Organisms: survival, fecundity, growth	Many EPA programs rely on organism-level attributes of survival, fecundity, and growth in assessing ecological risks (e.g., water quality criteria, pesticide and toxic chemical reviews, Superfund sites). Organism-level species protection is mandated by the Endangered Species Act, Marine Mammal Protection Act, Bald Eagle Protection Act, and Migratory Bird Treaty Act.	Results of toxicity tests of the survival, fecundity, and growth of organisms are abundant and often can be extrapolated to endangered species and other species of concern. Information on the ranges of listed endangered species is available through state and federal governments.
Population-level endpoints			
4	Assessment population: extirpation	EPA has taken action or provided guidance to prevent extirpation of local populations (e.g., assessment of likelihood of extirpation of fish populations due to acid rain). See also the description for Assessment population: abundance.	Extirpation can be predicted using population viability analysis. Demonstrating extirpation may be easy or difficult, depending on the conspicuousness of a species. See also the description for Assessment population: abundance.

Table 2-2. Generic ecological assessment endpoints (GEAEs): summary of the policy support for their use and their practicality[a] (continued)

GEAE #	Entity: attribute(s)	Policy support	Practicality
5	Assessment population: abundance	Major environmental statutes mandate protection of animals, plants, aquatic life, and living things generally, which can be inferred to entail protection of populations. EPA policies for pesticides, toxic chemicals, hazardous wastes, and air and water pollutants are intended to protect assessment populations of organisms. Mammals, birds, fish, aquatic invertebrates, and plants are typically assessed.	Changes in abundance may be predicted using conventional toxicity data with statistical extrapolation models and population models. OPPT evaluated a population model to explore effects of chloroparaffins on fish populations. Measurement of abundance in the field may be easy or difficult, depending on the species.
6	Assessment population: production	See description for Assessment population: abundance. Additionally, a number of laws are intended to maintain production of various economically valuable species. EPA water programs (e.g., National Estuary Program) and air programs (e.g., criteria pollutant standards) have involved protecting production of resource species populations.	Changes in production may be predicted using conventional toxicity data as well as population-based approaches. For resource species such as tree or fish species, production changes may be measurable in the field but may require long periods of observation.
Community and ecosystem-level endpoints			
7	Assessment communities, assemblages, and ecosystems: taxa richness	EPA water quality biocriteria frequently incorporate measures of community taxa richness. Additionally, EPA testing for pesticides, toxic chemicals, and water pollutants is intended to assess impacts to communities as well as populations and organisms. Fish, aquatic invertebrates, and aquatic plant assemblages are often assessed.	Changes in communities can be inferred or modeled from conventional toxicity data. Measuring taxa richness and abundance of aquatic communities, at least for fish and macroinvertebrate communities, is practical and well established. Ecosystem models that assess effects of toxicants on community properties are available and can use data acquired from organism-level laboratory testing, but they have not been routinely applied to date.
8	Assessment communities, assemblages, and ecosystems: abundance	As in the case of taxa richness, water quality biocriteria incorporate measures of community abundance, and EPA testing protocols are intended to assess impacts to communities.	See description above for taxa richness within assessment communities.

Table 2-2. Generic ecological assessment endpoints (GEAEs): summary of the policy support for their use and their practicality[a] (continued)

GEAE #	Entity: attribute(s)	Policy support	Practicality
9	Assessment communities, assemblages, and ecosystems: plant production	EPA water quality policies address overproduction of aquatic plants (and concomitant eutrophication) due to excess input of nutrients. EPA policies for pesticides, toxic chemicals, water pollutants, and air pollutants (as in the case of ozone and acid rain) also target decreases in production of forests or other plant communities.	Methods for measuring plant production are well developed for both terrestrial and aquatic communities. Methods for predicting effects of nutrient addition are relatively well developed. Protocols for testing plant toxicity are available and include production metrics.
10	Assessment communities, assemblages, and ecosystems: area	Policy support exists for considering the area of wetlands, coral reefs, and endangered/rare ecosystems. Among the supports for wetlands protection are the Clean Water Act, the National Environmental Policy Act (NEPA), the Coastal Zone Management Act, Executive Order 11990, and the federal wetlands delineation manual.[b] Policies for protection of coral reefs are established by Executive Order 13089; additional support may be found in the Coastal Zone Management Act and the Marine Protection, Research, and Sanctuaries Act. Many U.S. coral reefs are protected by state or federal government. Fewer EPA precedents exist for endangered/ rare ecosystems, but a variety of EPA programs have considered them, e.g., Superfund and NEPA.	Assessing the area of communities is generally straightforward, although when clear boundaries between communities are absent, defining areas may be somewhat difficult. Methods for delineating wetlands are well established, and changes in wetland area are therefore relatively easy to measure and monitor over time. The area of coral reefs is also relatively easy to determine. In the case of endangered and rare ecosystem types, a ready data source is NatureServe[c], which maintains data on all known U.S. ecological communities, ranked from critically imperiled to secure. Prediction of change from one community or ecosystem type to another may be difficult.
11	Assessment communities, assemblages, and ecosystems: function	Policy support for ecosystem function is primarily limited to wetlands. The support for wetland protection cited above for community/ecosystem area generally applies to wetland function as well.	Loss of wetland function can be inferred from loss of wetland area. However, losses of function independent of area loss generally are not readily observable or predictable.

Table 2-2. Generic ecological assessment endpoints (GEAEs): summary of the policy support for their use and their practicality[a] (continued)

GEAE #	Entity: attribute(s)	Policy support	Practicality
12	Assessment communities, assemblages, and ecosystems: <u>physical structure</u>	The primary policy support for this endpoint derives from the Clean Water Act, which applies to aquatic ecosystems. Restoring and maintaining the physical integrity (along with the chemical and biological integrity) of the nation's waters is the primary goal of the Clean Water Act. EPA policies and monitoring guidance under the Act include measures of physical structure.	Protocols exist for measuring many of the physical characteristics of aquatic ecosystems. The impacts of many actions (e.g., channelization, dam construction) on the physical structure of water bodies can be readily predicted. Other effects (such as hydrology changes due to land use changes) are more difficult, but still possible, to model.
Officially designated endpoints			
13	Critical habitat for threatened and endangered species: <u>area</u>	The Endangered Species Act specifically mandates the protection of critical habitat for endangered species in addition to the species themselves. The area (quantity) of available habitat is commonly used in assessing risks to these species.	Information on habitat used by listed species is available from state and federal agencies, although critical habitat has not been officially designated for most listed species. Generally it is practical to determine effects on habitat area.
14	Critical habitat for threatened and endangered species: <u>quality</u>	Legal protection of critical habitat extends to the quality (suitability) of the habitat to endangered species, in addition to its extent.	Assuming that critical habitat can be identified (even if not officially designated), it generally should be practical to determine whether it has been or will be adversely modified.
15	Special places: <u>ecological properties that make them special or legally protected</u>	The Clean Air Act, NEPA, and other statutes require protection of special places such as national parks, wilderness areas, and wildlife refuges, and this is reflected in EPA policies. The Clean Water Act gives EPA a role in designating national estuaries and outstanding national resource waters, which receive additional protection.	Special places and their important ecological properties usually can be defined readily. The ability to predict or detect impacts to these properties will depend on the nature of the properties and whether impacts are direct or indirect.

[a]See Appendix A for details and references.
[b]Environmental Laboratory (1987)
[c]NatureServe's web address is <http://www.natureserve.org>.

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Guidelines for Ecological Risk Assessment

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Risk Assessment Forum

articulated management goals, (2) characterization of decisions to be made within the context of the management goals, and (3) agreement on the scope, complexity, and focus of the risk assessment, including the expected output and the technical and financial support available to complete it.

2.2.1. Management Goals

Management goals are statements about the desired condition of ecological values of concern. They may range from “maintain a sustainable aquatic community” (see text boxes 2-5 and 2-6) to “restore a wetland” or “prevent toxicity.” Management goals driving a specific risk assessment may come from the law, interpretations of the law by regulators, desired outcomes voiced by community leaders and the public, and interests expressed by affected parties. All involve input from the public. However, the process used to establish management goals influences how well they provide guidance to a risk assessment team, how they foster community participation, and whether the larger affected community will support implementation of management decisions to achieve the goal.

Text Box 2-5. Sustainability as a Management Goal

To sustain is to keep in existence, maintain, or prolong. Sustainability is used as a management goal in a variety of settings (see U.S. EPA, 1995a). Sustainability and other concepts such as biotic or community integrity may be very useful as guiding principles for management goals. However, in each case these principles should be explicitly defined and interpreted for a place to support a risk assessment. To do this, key questions need to be addressed: What does sustainability or integrity mean for the particular ecosystem? What must be protected to meet sustainable goals or system integrity? Which ecological resources and processes are to be sustained and why? How will we know we have achieved it? Answers to these questions serve to clarify the goals for a particular ecosystem. Concepts like sustainability and integrity do not meet the criteria for an assessment endpoint (see section 3.3.2).

A majority of Agency risk assessments incorporate legally established management goals found in enabling legislation. In these cases, goals were derived through public debate among interested parties when the law was enacted. Such management goals (e.g., the Clean Water Act goals to “protect and restore the chemical, physical and biological integrity of the Nation’s waters”) are often open to considerable interpretation and rarely provide sufficient guidance to a risk assessor. To address this, the Agency has interpreted these goals into regulations and guidance for implementation at the national scale (e.g., water quality criteria, see text box 3-17). Mandated goals may be interpreted by Agency managers and staff into a particular risk assessment format and then applied consistently across stressors of the same type (e.g., evaluation of new chemicals). In cases where laws and regulations are specifically applied to a particular site, value-based management goal or desired state. As environmental protection efforts shift from implementing controls toward achieving measurable environmental results, value-based management goals at the national scale will be increasingly important as guidance for risk assessors. Such goals as "no unreasonable effects on bird survival" or "maintaining areal extent of wetlands" will provide a basis for risk assessment design (see also U.S. EPA, 1997a, for additional examples and discussion).

The "place-based" or "community-based" approach for managing ecological resources recommended in the Edgewater Consensus (U.S. EPA, 1994b) generally requires that management goals be developed for each assessment. Management goals for "places" such as watersheds are formed as a consensus based on diverse values reflected in Federal, State, tribal, and local regulations and on constituency-group and public concerns. Public meetings, constituency-group meetings, evaluation of resource management organizational charters, and other means of looking for shared goals may be necessary to reach consensus among these diverse groups, commonly called "stakeholders" (see text box 2-3). However, goals derived by consensus are normally general. For use in a risk assessment, risk assessors must interpret the goals into more specific objectives about what must occur in a place in order for the goal to be achieved and identify ecological values that can be measured or estimated in the ecosystem of concern (see text box 2-6). For these risk assessments, the interpretation is unique to the ecosystem being assessed and is done on a case-by-case basis as part of the planning process. Risk assessors and risk managers should agree on the interpretations.

Early discussion on and selection of clearly established management goals provide risk assessors with a fuller understanding of how different risk management options under consideration may result in achieving the goal. Such information helps the risk assessor identify and gather critical data and information. Regardless of how management goals are established, those that explicitly define ecological values to be protected provide the best foundation for identifying actions to reduce risk and generating risk assessment objectives. The objectives for the risk assessment derive from the type of management decisions to be made.

2.2.2. Management Options to Achieve Goals

Risk managers must implement decisions to achieve management goals (see text box 2-7). These risk management decisions may establish national policy applied consistently across the country (e.g., premanufacture notices [PMN] for new chemicals, protection of endangered species) or be applied to a specific site (e.g., hazardous waste site cleanup level) or management concern (e.g., number of combined sewer overflow events allowable per year) intended to achieve an environmental goal when implemented. Management decisions often begin as one of

3.1. PRODUCTS OF PROBLEM FORMULATION

Problem formulation results in three products: (1) assessment endpoints that adequately reflect management goals and the ecosystem they represent, (2) conceptual models that describe key relationships between a stressor and assessment endpoint or between several stressors and assessment endpoints, and (3) an analysis plan. The first step toward developing these products is to integrate available information as shown in the hexagon in figure 3-1; the products are shown as circles. While the assessment of available information is begun up front in problem formulation and the analysis plan is the final product, the order in which assessment endpoints and conceptual models are produced depends on why the risk assessment was initiated (see section 3.2). To enhance clarity, the following discussion is presented as a linear progression. However, problem formulation is frequently interactive and iterative rather than linear. Reevaluation may occur during any part of problem formulation.

3.2. INTEGRATION OF AVAILABLE INFORMATION

The foundation for problem formulation is based on how well available information on stressor sources and characteristics, exposure opportunities, characteristics of the ecosystem(s) potentially at risk, and ecological effects are integrated and used (see figure 3-1). Integration of available information is an iterative process that normally occurs throughout problem formulation. Initial evaluations often provide the basis for generating preliminary conceptual models or assessment endpoints, which in turn may lead risk assessors to seek other types of available information not previously recognized as needed.

The quality and quantity of information determine the course of problem formulation. When key information is of the appropriate type and sufficient quality and quantity, problem formulation can proceed effectively. When data are unavailable, the risk assessment may be suspended while additional data are collected or, if this is not possible, may be developed on the basis of what is known and what can be extrapolated from what is known. Risk assessments are frequently begun without all needed information, in which case the problem formulation process helps identify missing data and provides a framework for further data collection. Where data are few, the limitations of conclusions, or uncertainty, from the risk assessment should be clearly articulated in risk characterization (see text box 3-2).

The impetus for an ecological risk assessment influences what information is available at the outset and what information should be collected. For example, a risk assessment can be initiated because a known or potential stressor may enter the environment. Risk assessors

responses determines whether the risk assessment is still relevant to management decisions about an assessment endpoint. As an example, an assessment may be conducted to evaluate the
potential risk of a pesticide used on seeds to an endangered species of seed-eating bird. The assessment endpoint entity is the endangered species. Example attributes include feeding behavior, survival, growth, and reproduction. While it may be possible to directly collect measures of exposure and assessment endpoint life-history characteristics on the endangered species, it would not be appropriate to expose the endangered species to the pesticide to measure sensitivity. In this case, to evaluate susceptibility, the most appropriate surrogate measures would be on seed-eating birds with similar life-history characteristics and phylogeny. While insectivorous birds may serve as an adequate surrogate measure for determining the sensitivity of the endangered bird to the pesticide, they do not address issues of exposure.

Problem formulations based on assessment endpoints and selected measures that address both sensitivity and likely exposure to stressors will be relevant to management concerns. If assessment endpoints are not susceptible, their use in assessing risk can lead to poor management decisions (see section 3.3.1). To highlight the relationships among goals, assessment endpoints, and measures, text box 3-

Text Box 3-16. Examples of a Management Goal, Assessment Endpoint, and Measures

Goal: Viable, self-sustaining coho salmon population that supports a subsistence and sport fishery.

Assessment Endpoint: Coho salmon breeding success, fry survival, and adult return rates.

Measures of Effects

- Egg and fry response to low dissolved oxygen
- Adult behavior in response to obstacles
- Spawning behavior and egg survival with changes in sedimentation

Measures of Ecosystem and Receptor Characteristics

- Water temperature, water velocity, and physical obstructions
- Abundance and distribution of suitable breeding substrate
- Abundance and distribution of suitable food sources for fry
- Feeding, resting, and breeding behavior
- Natural reproduction, growth, and mortality rates

Measures of Exposure

- Number of hydroelectric dams and associated ease of fish passage
- Toxic chemical concentrations in water, sediment, and fish tissue.
- Nutrient and dissolved oxygen levels in ambient waters
- Riparian cover, sediment loading, and water temperature